

LOW NOISE OPTICAL HOUSINGREFERENCE TO RELATED APPLICATION

[0001] This application claims the benefit of U.S. Provisional Application No. 60/400,177, August 1, 2002. The present application incorporates the foregoing disclosures herein by reference.

BACKGROUND OF THE INVENTION

[0002] Pulse oximetry is a widely accepted noninvasive procedure for measuring the oxygen saturation level of arterial blood, an indicator of a person's oxygen supply. Early detection of low blood oxygen level is critical in the medical field, for example in critical care and surgical applications, because an insufficient supply of oxygen can result in brain damage and death in a matter of minutes. FIG. 1 illustrates a pulse oximetry system **100** having a sensor **110** applied to a patient, a monitor **160** and a patient cable **140** connecting the sensor **110** and the monitor **160**. The sensor **110** is attached to a tissue site, such as an adult patient's finger (as shown). Other sensor types are configured to attach, say, to a neonatal patient's foot. The sensor **110** is configured with both red and infrared LEDs **112** (hidden) that, for finger attachment, project light through the fingernail and into the blood vessels and capillaries underneath. A photodiode **114** (not visible) is positioned at the finger tip opposite the fingernail so as to detect the LED emitted light as it emerges from the finger tissues.

SUMMARY OF THE INVENTION

[0003] FIG. 2 illustrates various optical noise sources for a sensor **110** (FIG. 1). Shown is the placement of the sensor LEDs **112** and detector **114** on a finger without showing the associated electrical interconnections, base stock and face stock materials. Emitted light **210** is projected from the LEDs **112** into the fingernail bed. Received light **220** propagates through the finger tissues to the detector **114**, subject to absorption and scattering, to generate a desired sensor signal. Light which illuminates the detector **114** without propagating through the finger is unwanted optical "noise" that corrupts the desired sensor signal. Noise sources include ambient light **230** and piped light **240**. Ambient light **230** is

transmitted to the detector 114 from external light sources, i.e. light sources other than the LEDs 112. Piped light 240 is stray light from the LEDs 112 that is transmitted around a tissue site along a light conductive surface, such as a reflective inner surface of face stock material, directly to the detector 114. Light piping and light piping reduction are described in U.S. Patent No. 5,782,757 entitled "Low Noise Optical Probe," which is assigned Masimo Corporation, Irvine, CA and incorporated by reference herein.

[0004] FIG. 3 illustrates a prior art low noise sensor 300. The sensor 300 has a detector 310, a spacer 330 and an optical shield 350. The detector 310 is configured to receive light 220 that has propagated through a tissue site 10, as described with respect to FIGS. 1-2, above. The spacer 330 is positioned between the tissue site 10 and the detector 310, providing an optical barrier so as to reduce the intensity of piped light 240 that reaches the detector 310. The spacer 330 defines an aperture 332 that allows a transmitted portion 360 of propagated light 220 to reach the detector 310. A blocked portion 370 of propagated light 220 is reflected back into the tissue and/or absorbed by the spacer 330, depending upon the spacer material. The optical shield 350 may be a metal foil or other opaque material that prevents ambient light 230 from reaching the detector 310. Further, the detector 310, spacer 330 and optical shield 350 may be enclosed in a housing (not shown) of opaque material that further prevents ambient light 230 from reaching the detector 310. A low noise sensor is described in U.S. Patent No. 5,782,757, cited above.

One aspect of a low noise optical housing is a substrate having a reflective side and an absorptive side. The substrate has a generally planar base portion and a protruding cover portion. The cover portion defines a pocket on the absorptive side. The substrate has an open position with the base portion distal the cover portion and a closed position with the base portion proximate the cover portion. The substrate is configured to enclosed a detector within the pocket in the closed position. The base portion defines an aperture generally centered within the base portion and aligned with the detector in the closed position so as to pass light through to the detector.

[0005] Another aspect of a low noise optical housing is a method comprising the steps of providing a substrate having an absorptive side and a reflective side and forming a cover portion of the substrate so as to create a pocket on the absorptive side. Further steps

include punching the substrate so as to separate a housing from the substrate, securing a detector within the pocket, and enclosing the detector with the housing.

[0006] A further aspect of a low noise optical housing comprises a light reflecting cover means for shielding against ambient light and a base means for blocking piped light. The base means adjoins the cover means. The housing also comprises a light absorbing pocket means for securing a detector. The pocket means is defined by the cover means and the base means. The housing further comprises an aperture means for allowing light transmitted through a tissue site to be received by the detector. The aperture means is defined by the base means.

[0007] One aspect of a sensor circuit comprises a circuit substrate, a pair of pads disposed on an optical portion of the circuit substrate, a plurality of pinouts disposed on a connector portion of the circuit substrate, and a plurality of conductive paths providing electrical communication between the pads and the pinouts. The pads are configured to mechanically mount a corresponding pair of optical components to the circuit substrate and to electrically connect the components to the conductive paths. At least one of the pads is adapted to mount one of the components at either a first spacing or a second spacing from another one of the components. The second spacing is greater than the first spacing by a predetermined amount.

[0008] Another aspect of a sensor circuit comprises a flexible circuit substrate, a first pad disposed on the circuit substrate and configured to mount a detector, and a second pad disposed on the circuit substrate and configured to mount an emitter. At least one of the first pad and the second pad are adapted so that a detector-emitter spacing is a first distance or a second distance depending on the placement of at least one of the detector and the emitter. The first distance and the second distance are predetermined so as to accommodate particular sensor types.

[0009] A further aspect of a sensor circuit is a method comprising the step of predetermining a plurality of optical component spacings based upon a corresponding plurality of sensor types. The sensor types are indicative of tissue site location and patient size. Further steps are configuring a pad to fixedly mount and electrically connect an optical component to a flexible circuit at a plurality of positions, where the positions correspond to

the spacings, and mounting the optical component to a particular one of the positions to construct a particular one of the sensor types.

[0010] An additional aspect of a sensor circuit is a sensor comprising a circuit substrate means for mounting and electrically connecting components and a pad means disposed on the circuit substrate for fixedly mounting an emitter at either a first spacing or at a second spacing from a detector. The sensor also comprises a tape stock means for attaching the emitter and the detector to a tissue site.

[0011] For purposes of summarizing the invention, certain aspects, advantages and novel features of the invention have been described herein. Of course, it is to be understood that not necessarily all such aspects, advantages or features will be embodied in any particular embodiment of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0012] A general architecture that implements the various features of the invention will now be described with reference to the drawings. The drawings and the associated descriptions are provided to illustrate embodiments of the invention and not to limit the scope of the invention. Throughout the drawings, reference numbers are re-used to indicate correspondence between referenced elements. In addition, the first digit of each reference number indicates the figure in which the element first appears.

[0013] FIG. 1 is a perspective view of a prior art pulse oximetry system;

[0014] FIG. 2 is a diagram illustrating optical noise sources and a prior art sensor;

[0015] FIG. 3 is a diagram illustrating optical noise sources and a prior art reduced noise sensor;

[0016] FIGS. 4A-C are top, side cross-section and front cross-section views, respectively, of a low noise optical housing;

[0017] FIGS. 5A-B are top and side views of a low noise optical housing in an open position;

[0018] FIGS. 5C-D are top and side views of a low noise optical housing in a closed position;

[0019] FIGS. 6A-B are detailed side views of alternative embodiments of a low noise optical housing enclosing a detector;

[0020] FIGS. 7A-B are top and perspective views, respectively, of an assembled pulse oximetry sensor configured for a neonate and incorporating a low noise optical housing;

[0021] FIG. 7C is a perspective view of an assembled pulse oximetry sensor configured for an adult and incorporating a low noise optical housing;

[0022] FIGS. 8A-B are exploded perspective views of neonate and adult flexible circuit assemblies, respectively, configured for a low noise optical housing;

[0023] FIGS. 9A-B are perspective views of a neonate sensor assembly showing installation of a low noise optical housing;

[0024] FIGS. 9C-D are perspective views of an adult sensor assembly showing installation of a low noise optical housing;

[0025] FIGS. 10A-C are detailed perspective views of an unassembled, a partially assembled and a fully assembled EMI shield, respectively, prior to low noise optical housing installation;

[0026] FIGS. 11A-B are detailed top and bottom views of a neonate or infant sensor optical assembly;

[0027] FIGS. 11C-E are detailed top views of an adult or pediatric sensor optical assembly;

[0028] FIG. 11C shows an optical assembly without the emitter installed;

[0029] FIG. 11D shows an optical assembly with pediatric detector-emitter spacing; and

[0030] FIG. 11E shows an optical assembly with adult detector-emitter spacing; and

[0031] FIGS. 12A-B are exploded perspective views of multiple neonate sensor and adult sensor assemblies, respectively, showing base stock and face stock installation.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[0032] FIGS. 4A-C illustrate a low noise optical housing 400 having a protruding cover 410, a generally flat flange 420 disposed around the periphery of the cover 410, and a generally flat base 460 adjoining the flange 420. The housing 400 is configured to accept a detector 820 (FIGS. 6A-B) and provide ambient light and piped light reduction. In particular, the low noise optical housing 400 advantageously incorporates the functions of a light barrier, opaque cover, spacer and aperture, as described with respect to FIG. 3, above, in a relatively small, easy to manufacture, one-piece design.

[0033] As shown in FIGS. 4B-C, the housing 400 is advantageously constructed of a flat substrate which, in one embodiment, is a laminate of two materials including an outer white layer 407 and an inner black layer 408. By utilizing a laminate of both white and black material, the low noise optical housing 400 advantageously functions both as a light absorber and as a light reflector. The white layer 407 acts as a reflector, reflecting unwanted ambient light outward from a detector enclosed in the housing, as described below, as well as reflecting emitter source light back into a patient tissue site. The reflected ambient light reduces noise and the reflected source light increases the sensor current transfer ratio. The black layer 408 absorbs unwanted ambient light, preventing it from reaching the enclosed detector 820 (FIGS. 6A-B). The two materials 407, 408 are laminated together before the housing 400 is formed and shaped. The housing 400 is vacuum formed on a flat blank of the laminated material to create a cover 410, as described below. The housing 400, aperture 470 and slot 480, as described below, are then punched out and the housing 400 is removed from the remainder of the laminated material.

[0034] In an alternative embodiment, the housing 400 is formed from a black substrate, which is painted white on the outside, i.e. the side corresponding to the outer white layer 407, or otherwise coated on the outside with a reflecting material or substance. In another alternative embodiment, the housing 400 is formed from a white substrate, which is painted black on the inside, i.e. the side corresponding to the inner black layer 408, or otherwise coated on the inside with an absorbing material or substance.

[0035] As shown in FIGS. 4A-C, the cover 410 has a ramp 412 sloping from the flange 420 to a generally level platform 414 raised above the flange 420. The cover 410 also

has beveled sides 418 and a beveled back 419 that slope from the flange 420 inward to the platform 414. The cover 410 defines an pocket 440 for securing a detector 820 (FIGS. 6A-B), as described below. The flange 420 has indents 422 that gradually taper from the wider flange width 502 (FIG. 5A) to that of the narrower base width 503 (FIG. 5A).

[0036] Also shown in FIGS. 4A-C, the base 460 defines a generally centered aperture 470 and a slot 480 proximate the flange 420, partially extending across the base width 503 (FIG. 5A). In a closed position, as described with respect to FIGS. 5C-D, below, the base 460 provides a bottom for the cover 410 and pocket 440 and optically shields the detector 820 (FIGS. 6A-B). The base 460 also provides a spacer and aperture to reduce light piping. The slot 480 allows the base 460 to be easily folded so that the aperture 470 is in proper alignment with the detector active area. Further, the narrower base width 503 (FIG. 5A) allows the flange 420 to overlap the base 460 in the closed position 560 (FIGS. 5C-D) so as to seal the housing edges from ambient light. The flange 420 also provides structure for attaching the housing 400 to a tape stock layer (FIGS. 12A-B).

[0037] FIGS. 5A-D illustrate the housing 400 in an open position 510 (FIGS. 5A-B) and a closed position 560 (FIGS. 5C-D). As shown in FIGS. 5A-B, in an open position 510 the housing 400 has an overall length 501, a flange width 502, a base width 503 and a thickness 504. The flange width 502 is greater than the base width 503. In one embodiment, the housing length 501 is less than about 1.1 inches, the flange width 502 is less than about .4 inches and the housing thickness 504 is less than about .015 inches. As shown in FIGS. 5A-D, from an open position 510, the housing 400 is folded to the closed position 560 along the slot 480 and across the base width 503 proximate to each indent 422. In the closed position 560, the housing 400 provides an optical enclosure for a detector, as described with respect to FIGS. 6A-B, below.

[0038] FIGS. 6A-B illustrate shielded detector assemblies 1000 incorporating flat aperture 400 and raised aperture 600 embodiments, respectively, of a low noise optical housing. A detector 820 is enclosed in the optical housing 400, 600 so that the active area of the photodiode chip 821 is aligned with the housing aperture 470, 670. An EMI shield 1010, described with respect to FIGS. 10A-C, below, also encloses the detector 820, and a corresponding flexible circuit assembly 801, described with respect to FIGS. 8-9, below, exits

the housing 400, 600 between the base 460, 660 and the flange 420, 620. As shown in FIG. 6B, the raised aperture housing 600 includes a raised aperture portion 662 that extends from the plane of the base 660 so as to advantageously provide a larger spacing between the detector 820 and a tissue site, further reducing the effects of light piping.

[0039] FIGS. 7A-B illustrate an assembled pulse oximetry neonate sensor 700. The sensor 700 includes an optical end 701, an elongated body 703 and a connector end 705. The optical end 701 incorporates a detector assembly 1000 (FIGS. 10A-C), described below, including a low noise optical housing 400 (FIGS. 6A-B), as described above. The body 703 includes signal traces (not visible) between the optical end 701 and the connector end 705. The connector end 705 has a plug portion configured to insert into a mating patient cable connector so as to mechanically and electrically connect the sensor 700 to a patient cable 140 (FIG. 1), for example. A patient cable connector is described in U.S. Patent No. 6,152,754 entitled "Circuit Board Based Cable Connector," which is assigned to Masimo Corporation, Irvine, CA and incorporated by reference herein.

[0040] FIG. 7C illustrates an assembled pulse oximetry adult sensor 750. The sensor 750 includes an end wrap 751, a body 753 including an optical section 754, a middle wrap 755, and a connector end 759. The optical section 754 incorporates a detector assembly 1000 similar in construction to that described in FIGS. 10A-C, below, including a low noise optical housing 400 (FIGS. 6A-B), as described above. The sensor 750 includes signal traces (not visible) between the optical section 754 and the connector end 759. The connector end 759 is similar to that described with respect to FIGS. 7A-B, above. A pulse oximetry adult sensor having end and middle wraps and an electromagnetic interference (EMI) shield is described in U.S. Patent Application No. 10/137,942, filed May 2, 2002, entitled "Flex Circuit Shielded Optical Sensor," assigned to Masimo Corporation, Irvine, CA and incorporated by reference herein.

[0041] FIGS. 8-12 illustrate assembly of a neonate sensor 700 (FIGS. 7A-B) and an adult sensor 750 (FIG. 7C) including component attachment (FIGS. 8A-B), detector EMI shielding and optical shielding (FIGS. 9-11), and tape stock assembly (FIGS. 12A-B). FIG. 8A illustrates a neonate sensor circuit assembly 800 including multiple, duplicate flexible circuit assemblies 801 each having a flexible circuit substrate 810 and associated components soldered

or otherwise electrically connected to the flexible circuit substrate 810, as is well known in the art. Each flexible circuit assembly 801 includes a detector 820 and an emitter 830. The detector 820 is enclosed in an EMI shield 1010, described in further detail with respect to FIGS. 10A-C, below. The emitter 830 is connected to a pad 1110 having multiple contact sets, described in further detail with respect to FIG. 11A, below. Each assembly 801 may also include an information element 840, which can be read by an attached pulse oximeter 160 (FIG. 1). The information element 840 may provide information regarding the sensor 700, such as sensor type or manufacturer to name a few. An information element is described in U.S. Patent No. 6,397,091, entitled "Manual and Automatic Probe Calibration," assigned to Masimo Corporation, Irvine, CA and incorporated by reference herein.

[0042] FIG. 8B illustrates an adult sensor circuit assembly 850 likewise including multiple, duplicate flexible circuit assemblies 851 each having a flexible circuit substrate 860 and associated components soldered or otherwise electrically connected to the flexible circuit substrate 860, including a detector 820, an emitter 830 and maybe an information element 840, such as described with respect to FIG. 8A, above. The detector 820 is enclosed in an EMI shield 1010, such as described with respect to FIGS. 10A-C, below. In one embodiment, the emitter 830 is connected to a pad 1160 (FIGS. 11C-E) having extended contacts, as described below.

[0043] FIGS. 9A-B illustrate a neonate sensor assembly 900 having a flexible circuit assembly 801, a low noise optical housing 400 and a connector tab 910. The sensor assembly 900 is configured as an optical portion 1100, which is described in further detail with respect to FIGS. 11A-B, below, and a connector portion 901. The optical portion 1100 has an emitter 830 and a shielded detector assembly 1000, described in further detail with respect to FIGS. 10A-C. The connector portion 901 is configured with the connector tab 910 supporting sensor pinouts 920.

[0044] FIGS. 9C-D illustrate an adult sensor assembly 950 having a flexible circuit assembly 851, a low noise optical housing 400 and a connector tab 910. The sensor assembly 950 is configured as an optical portion 1150, described in further detail with respect to FIGS. 11C-E, below, and a connector portion 901, as described above. The optical portion 1150 has

an emitter 830 and a shielded detector assembly 1000, such as is described in detail with respect to FIGS. 10A-C.

[0045] FIGS. 10A-C illustrate a shielded detector assembly 1000 configured for the neonate flexible circuit assembly 801 (FIGS. 8A, 9A-B) as shown, or, similarly, for the adult flexible circuit assembly 851 (FIGS. 8B, 9C-D). As shown in FIG. 10A, inside pressure sensitive adhesive (PSA) 1020 and top PSA 1030 are removed from a foldable shield 1010, and bottom PSA 1040 is removed from a fixed shield 1005 (not visible). As shown in FIG. 10B, the shield 1010 is next folded toward the detector 820. As shown in FIG. 10C, the shield 1010 is then folded over the back and sides of the detector 820, enclosing the detector 820. The inside PSA 1020 adheres to the detector 820, maintaining the foldable shield 1010 in place. Next, the EMI shielded detector 820 is placed into the optical housing 400. The top PSA 1030 adheres to the inside surface of the optical housing 400, which defines a pocket 440 (FIGS. 4B-C) as described above. The bottom PSA 1040 adheres to the optical housing base 410 (FIGS. 4A-C), maintaining the detector 820 in place within the optical housing cover 410 (FIGS. 4A-C), aligned with the aperture 470 (FIG. 4A), and maintaining the optical housing 400 in the closed position 560 (FIGS. 5C-D).

[0046] FIGS. 11A-B illustrate one embodiment of the optical portion 1100 of a sensor assembly 900 (FIGS. 9A-B) having a detector assembly 1000 and an emitter 830 connected to a pad 1110. As shown in FIG. 11A, a particular embodiment of the pad 1110 advantageously has an inner contact set 1112 and an outer contact set 1114. The emitter 830 may be attached and electrically connected in a first position to the inner contact set 1112 or in a second position to the outer contact set 1114. As shown in FIG. 11B, this advantageously provides two different detector-emitter spacings 1131, 1132 on the same flexible circuit substrate. A comparatively wider spacing 1131 corresponds to the second emitter position attached to the outer contact set 1114 (shown), and a comparatively narrower spacing 1132 corresponds to the first emitter position attached to the inner contact set 1112 (not shown). The choice of mounting the emitter with a narrower or wider spacing accommodates different sensor types for different sized patients or different tissue site thicknesses with fewer unique sensor parts or subassemblies. Note that the detector 820 (FIGS. 10A-B) is not visible in FIG. 11B as it is behind the fixed shield 1005. As an example, a neonate sensor 700 (FIGS. 7A-B) and an

infant sensor (not illustrated) configured for different sized foot sites may be manufactured from a single flex circuit part. In a preferred embodiment, the inner pads are configured for a 20 mm detector-emitter spacing appropriate for a neonate, such as a child weighing under 3 kg and the outer pads **1114** are configured for a 25 mm detector-emitter spacing appropriate for an infant, such as a child weighing 3-10 kg.

[0047] In another embodiment of the optical portion **1100**, a reinforcing tape (not shown) is applied to the component side (shown in FIG. **11A**) of the flexible circuit between the detector assembly **1000** and the emitter **830** so as to increase the number of bend cycles before failure of that flexible circuit area and to improve electrostatic discharge (ESD) resistance. The reinforcing tape is disposed over at least the extent of the pad **1110**. In a particular embodiment, the reinforcing tape is .004 inch polypropylene.

[0048] FIGS. **11C-E** illustrate one embodiment of the optical portion **1150** of a sensor assembly **950** (FIGS. **9C-D**) having a detector assembly **1000** and an emitter **830** connected to a pad **1160** having extended contacts. The contacts are extended along the direction between the detector assembly **1000** and the emitter **830**, allowing the emitter to be mounted on the same pad **1160** in multiple positions. As shown in FIG. **11C**, the emitter **830** is installed over an elongated aperture **1170**. The extended pad area **1160** advantageously provides for different detector-emitter spacings **1181**, **1182** (FIGS. **11D-E**) on the same flexible circuit substrate. A comparatively narrower spacing **1181** corresponds to a first emitter position (FIG. **11D**), and a comparatively wider spacing **1182** corresponds to a second emitter position (FIG. **11E**). This accommodates different sensor types for different sized patients or different tissue site thicknesses with fewer unique sensor parts or subassemblies. As an example, an adult sensor **750** (FIGS. **7C**) and a pediatric sensor (not shown) configured for different sized finger sites may be manufactured from a single flex circuit part. As shown in FIGS. **11D-E**, in a preferred embodiment, the pad **1160** (FIG. **11C**) is configured with contacts that are extended at least 0.1 inches beyond an emitter **830** nominal lead length so as to accommodate a 1.0 inch detector-emitter spacing **1181** appropriate for a pediatric sensor or a 1.1 inch detector-emitter spacing **1182** appropriate for an adult sensor. The elongated aperture **1170** (FIG. **11C**) is configured accordingly, i.e. is elongated from a circular aperture sufficiently to accommodate either a 1.0 inch or a 1.1 inch detector-emitter spacing.

[0049] The ability to adjust the detector-emitter spacing on a particular flexible circuit so as to minimize the number of unique parts in manufacturing various sensor types and sizes is disclosed above. That disclosure is with respect to a pad 1110 (FIG. 11A) having multiple contact sets and a pad 1160 (FIG. 11C) having extended contacts with an associated elongated aperture 1170 (FIG. 11C). One of ordinary skill in the art will recognize other electrical and mechanical structures that allow such detector-emitter spacing adjustment. For example, although adjustment of the emitter 830 location relative to the detector 820 is achieved by the above-disclosed embodiments, adjustment of the detector 820 location relative to the emitter 830 may be achieved with similar structures. Further, adjustment of the detector-emitter spacing may also be achieved by altering the orientation of the detector 820 and/or the emitter 830. These adjustments may also be accommodated by multiple apertures rather than an elongated aperture. Although the sensors disclosed are based upon the detection of light transmitted through a tissue site, the ability to adjust detector-emitter spacing is equally applicable to reflectance sensors, i.e. sensors that are based upon the detection of light reflected from a tissue site.

[0050] FIG. 12A illustrates a tape stock assembly 1200 for a neonate sensor. In particular, multiple sensor assemblies 900 are sandwiched between a base stock 1210 and a face stock 1220. Individual completed sensors 700 (FIGS. 7A-B) are then cut from the tape stock assembly 1200. A base stock and a face stock are described in U.S. Patent No. 5,782,757, cited above.

[0051] FIG. 12B illustrates a tape stock assembly 1250 for an adult sensor. In particular, multiple sensor assemblies 950 are sandwiched between a base stock 1210 and a face stock 1220. Individual completed sensors 750 (FIGS. 7C) are then cut from the tape stock assembly 1250.

[0052] The low noise optical housing has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.

[0053] Additionally, all publications, patents, and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each

individual publication, patent, or patent application was specifically and individually indicated to be incorporated by reference.